

Appl. No. : 10/824,933  
Filed : April 15, 2004

### REMARKS

In response to the Office Action mailed July 7, 2006, Applicant respectfully requests that the Examiner reconsider the above-captioned patent application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 1-45 remain pending. Claims 1, 9, 12, and 31 have been amended. New Claims 41-45 have been added.

The results of the Office Action mailed July 12, 2006 are summarized as follows:

CLAIM NOS. (Original Claims)	DISPOSITION/REJECTION		
	BASIS	PRIMARY REFERENCE	SECONDARY REFERENCE(S)
1-8	103(a)	Wong US 6,312,888	n/a
9-12, 31-37	102(b)	Jina US 5,526,120	n/a
13, 38-39	103(a)	Jina US 5,526,120	Douglas US 5,962,215
14-18, 21	102(b)	Douglas US 5,962,215	n/a
19-20	103(a)	Douglas US 5,962,215	Wong US 6,312,888
22-23, 27-30	103(a)	Douglas US 5,962,215	Wong US 6,312,888 Jina US 5,526,120

#### Claim 1 vs. Wong (103(a))

Claim 1, as amended, includes the following language: "the sample chamber being reagentless." Wong teaches away from this feature. Wong teaches—in the "Field of the Invention" section at the very beginning of the application—that the invention "provides an article and method that monitors the amount of analyte in body fluid by means of a reagent that reacts with the analyte in the body fluid." Wong 1:12-15 (emphasis added).

Wong also teaches three "means for determining when the optical reading chamber contains a sufficient volume of sample." Wong 3:14-15. One means is a "colorant that is introduced into the optical reading chamber." Wong 3:17-18. Wong specifies that the "colorant must not be deposited in the optical path of the optical reading chamber," (Wong 10:12-14) and that the colorant "must be soluble or dispersible in the sample." (Wong 10:27-28). A second means is a reflective coating that is "washed away or dissolved by the sample." Wong 3:35-36; 11:28-31. A third means involves a hydrophilic membrane that is wetted by the sample. Wong 3:44-46. In each case, Wong

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teaches a substance that is present in a sample chamber, and that substance intermingles with and/or interacts with the sample in some way. As these examples show, Wong neither discloses nor suggests a "reagentless" sample chamber.

Dependent Claims 2-8 are patentable for at least the same reasons given above for independent Claim 1.

Claim 9 vs. Jina (102(b)):

The rejection of Claim 9 over Jina is incorrect because Jina teaches a "detectable means" 58/62 for ascertaining proper orientation and/or insertion of a test strip in a meter, not a physical property of the test strip. Thus, Jina does not teach "an identification key configured to indicate a physical property of the sample element."

Using the system taught in the Jina reference, a strip could be faulty or incorrect. As long as the strip was fully inserted into the device, a measurement could be taken, even though the strip itself (about which the detectable means 58/62 conveys nothing) was faulty or incorrect. The strip could thus have improper physical characteristics (e.g., incorrect absorption properties of the window, incorrect path length, incorrect sample chamber thickness, etc.) which could lead to inaccurate measurements, and the system would allow the user to proceed as if all was normal. For example, under the teachings of Jina, a counterfeit test strip that had been cut to the same shape and dimensions as a proper test strip would not be identified as counterfeit.

Applicant has also made minor amendments to Claim 9. Claim 9, as amended, is still not anticipated by Jina because Jina does not teach "an identification key in the optical path, the identification key comprising a physical property of the sample element," as required by the amended Claim 9.

Claim 10 is patentable for at least the reasons given above with respect to Claim 9. Furthermore, Figures 1 and 5-12 of Jina do not anticipate the additional limitation of Claim 10 because those figures merely show windows in an optical path. This does not disclose or suggest an "identification key in the optical path, the identification key comprising an optical absorption of a window in the optical path."

Claims 11 and 12 are patentable for at least the reasons given above with respect to Claim 9. Furthermore, Figures 7-12 of Jina do not anticipate the additional limitations of Claims 11 and 12; those figures merely show windows in an optical path. This neither discloses nor suggests an

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"identification key in the optical path, the identification key comprising" either of the following: "a thickness of a window in the optical path" or "a thickness of a sample chamber in the optical path."

Claim 14 vs. Douglas (102(b)):

Claim 14 is patentable for at least the reason that neither the reference code 61 nor the pattern 101 taught by Douglas indicates a "qualification state of the sample element." Instead, these provide "calibration data, timing sequence" and the like. Thus, while the calibration data can assist in obtaining an accurate reading of the sample, the calibration data does not indicate a "qualification state" of the sample element itself. Indeed, Douglas assumes that the test strip is suitable and does not even contemplate (let alone provide a possible test for identifying) a counterfeit or otherwise non-suitable test strip.

Dependent Claims 15-30 are patentable for at least the reasons provided here with respect to Independent Claim 14.

Claim 31 vs. Jina (102(b)):

The rejection of Claim 31 over Jina is incorrect for at least the reason that Jina does not disclose or suggest "qualifying the sample element by determining whether the sample element is of a type which is suitable for use with the analyte detection system." Jina provides for a "detectable means" 58/62 for ascertaining proper orientation and/or insertion of a test strip in a meter and is unconcerned with whether or not the test strip itself is qualified.

Jina teaches a "strip impeding wall 31" that is "designed to mate with the shape of the insertion end of the strip when the strip is properly inserted and to interfere with the insertion end of the strip when the strip is inserted upside down." Jina 7:13-18. Furthermore, under Jina's teachings, "any strip not fully inserted (irrespective of its orientation otherwise) will be recognized by the apparatus as an error." Jina 5:25-27.

Using the system taught in the Jina reference, a strip could be faulty or incorrect (or otherwise unqualified), but as long as the strip was fully inserted into the device, a measurement could be taken, even though the strip itself (about which the detectable means 58/62 conveys nothing) was faulty or incorrect. The strip could thus have improper physical characteristics (e.g., incorrect absorption properties of the window, incorrect path length, incorrect sample chamber

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thickness, etc.) which could lead to inaccurate measurements, and the system would allow the user to proceed as if all was normal.

Dependent Claims 32-37 are patentable for at least the reasons provided here.

### Conclusion

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is requested.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments, deletions and cancellations have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments, deletions and cancellations are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, David Jankowski, at (949) 721-2839 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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